



Food and Drug Administration  
Rockville, MD 20857

MAR 16 2012

Re: Invega Sustenna  
Patent No. 5,254,556  
Docket No. FDA-2009-E-0541

The Honorable David J. Kappos  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the patent term extension application for U.S. Patent No. 5,254,556 filed by Janssen, L.P., under 35 U.S.C. § 156. The patent claims Invega Sustenna (paliperidone palmitate), which was assigned new drug application (NDA) 22-264.

In the June 24, 2011, issue of the Federal Register (76 Fed. Reg. 37128), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before December 21, 2011, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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